**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br><br>***Cynthia Coffey, et al. v. Ethicon, Inc. et al.***<br><br>**Case No. 2:16-cv-09101** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**PLAINTIFF'S MEMORANDUM IN OPPOSITION OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

Plaintiff states as follows in opposition to Defendants' Motion for Summary Judgment:

## INTRODUCTION AND STANDARD OF LAW

In Defendants' Motion, they ignore evidence directly contrary to its arguments, and also ask the Court to extend California law beyond its authority. To succeed on its Motion, Ethicon, must show that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). On a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).[1]

## STATEMENT OF MATERIAL FACTS[2]

[1] Plaintiff agrees that the substantive law of California applies to Plaintiff's claims.
[2] Plaintiff disputes Defendants' version of Undisputed Facts to the extent they differ from Plaintiff's Statement of Material Facts.

Mrs. Cynthia Coffey was implanted with a Prolene Soft mesh on February 5, 2007 by Dr. Kenneth Griffis to treat her pelvic organ prolapse, in addition to a Burch procedure to treat her stress urinary incontinence. (Ex. A, Medical Records of Cynthia Coffey, at 2-5). Mrs. Coffey then began to experience a number of issues, including pelvic pain, dyspareunia, and stress urinary incontinence recurrence. (Ex. A at 6-10). On July 17, 2009, Mrs. Coffey underwent the implant of a Monarc midurethral sling to address her recurrent stress urinary incontinence. (Ex. A at 11-14).

Plaintiff continued to feel pelvic pain, dyspareunia, and recurrent stress urinary incontinence, so she went to Dr. Jean Park for treatment in 2012. (Ex. A at 15-20). On February 12, 2013, Mrs. Coffey was implanted with the TVT-Exact to treat her stress urinary incontinence. (Ex. A at 21-24). Her previous mesh was left in place as the placement of the new TVT-Exact did not interfere with the previous placement. (Ex. A at 22).

Mrs. Coffey continued to experience pain from mesh erosion, as well as dyspareunia and pelvic pain on her right side. (Ex. A at 25-44). Though she had a partial excision of the extruding mesh on November 15, 2017, she continued to experience dyspareunia, poking pain, as well as right lower quadrant pain and pelvic pain. (Ex. A. at 45-77).

In determining removal of both meshes, as previously indicated by both Dr. Griffis and Dr. Park, they provide the options for treatment for which the patients then choose from those options. (Ex. B, Deposition of Dr. Kenneth Griffis at 92:9-18; Ex. C, Deposition of Dr. Jean Park 94:11-23). Dr. Park recommended removal of the sling that was continuing to cause exposure as it would continue to cause pain, and since she had two slings both were to be removed. (Ex. C, Dep. Dr. Park at 137:12-20). Though Dr. Park was not able to determine whether any one mesh was the cause of the pain, Plaintiff notes that after removal of both of the meshes on August 22,

2018, her urinary symptoms and pain improved. (Ex. C, Dep. Dr. Park 107:19-22; 111:6-15; 137:25-138:1-13).

## ARGUMENT

### I. SUMMARY JUDGMENT IS NOT APPROPRIATE FOR PLAINTIFF'S FAILURE TO WARN CLAIM AND CAUSATION

Defendants argue that Plaintiff's claim fails under failure to warn and causation because Plaintiff did not meet burden of showing the inadequate warning and defects were a cause in producing her injuries. (Def. Mt. at 9). However, there is an abundance of evidence showing a genuine issue of material fact, and therefore Defendants' motion for summary judgement on this issue should be denied.

In California, when the learned intermediary doctrine applies, the plaintiff must show "…[1] that no warning was provided or the warning was inadequate, [and]…[2] that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer Inc.*, 196 F. Supp.2d 984, 991 (C.D. Cal. 2001) (*Motus I*) *aff'd sub nom. Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004) (*Motus II*). Courts in California have held that this duty to warn about the known or knowable hazards of a drug or medical device is ongoing. *See Singleton v. Eli Lilly Co.*, No. 1:10-cv-02019-AWI-SKO, 2012 WL 2018536 at *3 (E.D. Ca. June 5, 2012) ("The duty to warn is a continuing duty, requiring a manufacturer to notify the medical profession of any side effects of a prescription drug which are subsequently discovered, and is based on the application of scientific knowledge at the time of manufacture and distribution of the drug").

In order for a manufacturer of a drug or device to be absolved of liability, the warning it provides to the physician must be adequate. *See Conte v. Wyeth*, 168 Cal. App. 4th 89, 98, n.5 (Cal. App. 1, 2008).; *see also Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23, 29-30 (Cal. App. 2, 2010) (the warning provided to a sophisticated user was inadequate and, therefore, could

not absolve the defendant manufacturer of liability where neither the sophisticated user nor the manufacturer warned the plaintiff of the product at issue.) ("If Union Carbide and the sophisticated intermediary failed to give warnings, that should not absolve Union Carbide of responsibility.").

The adequacy of a warning is generally a question of fact. *Carlin v. Superior Court*, 56 Cal. Rptr. 2d 162, 168-69 (Cal. 1996). A warning is inadequate if it fails to "sufficiently alert the *user* to the possibility of danger." *Aguayo v. Crompton & Knowles Corp*., 228 Cal. Rptr. 768, 775 (Cal. Ct. App. 1986) (emphasis added). In a medical device case, the physician who implants the device is the "user." *Valentine v. Baxter Healthcare Corp*., 81 Cal. Rptr. 2d 252, 263 (Cal. Ct. App. 1999).

In this case of the Prolene Soft mesh, the IFU was insufficient for a physician such as Dr. Griffis to understand the frequency and severity of the adverse events involved.[3] Plaintiff's general expert Dr. Donald R. Ostergard, M.D prepared a report presenting that that IFUs were inadequate insofar as they lack substantive risk information presented to physicians such as Dr. Griffis. Particularly, the IFU does not warn of delayed visceral erosion and delayed intractable and untreatable pain. (Ex. E, Expert Report of Dr. Donald R. Ostergard, M.D. at 21). Plaintiff suffered injuries such as pelvic pain and dyspareunia after the implantation of the Prolene Soft Mesh (Ex. A at 6-10).

The IFUs were inadequate because they were completely void of these important risks, which is information that physicians would need to know to factor into an associated risk/benefit analysis. One specific example is the lack of information to doctors about the degradation of the

[3] The Defendants' IFU for the Prolene Soft at time of implantation indicated the adverse events to include: "infection potentiation, inflammation, adhesion formation, fistua formation, and extrusion." (attached hereto as Exhibit D)

Prolene mesh, and its ability to cause flaking and fissuring and cause moderate to severe vaginal retraction. (Ex. E at 19-20). The IFU also did not warn of persistent inflammatory reaction by the weakened and degraded mesh in the body. *Id*. These risks make the Prolene mesh "unreasonably dangerous, defective and [unsuitable] to serve as the permanent implants that they have been represented by Ethicon to be." (Ex. F, Jimmy W. Mays General Expert Report at 5).

Even though Dr. Griffis did not specifically rely on the IFU prior to the implantation of the Prolene Soft mesh in Mrs. Coffey, he did recall receiving materials from Johnson & Johnson in the past and those materials may have included information about the risks and benefits of their devices. (Ex. B, Dep. Dr. Griffis 82:3-16). Had Dr. Griffis known there were any increased risks that the Defendants knew regarding the Prolene Soft, he would have communicated it to his patients during the risks, benefits, and alternatives conversation prior to surgery, as he spends more time talking to clients about things that are more likely to occur or are more severe. (*Id.* at 91:17-24; 105:15-25-106:3).

In the case of the TVT-Exact, Ethicon did not adequately warn doctors or their patients about the frequency or severity of issues associated specifically with the TVT-Exact sling. Plaintiff's general expert Jerry G. Blavais, M.D prepared a report presenting that the Defendants inadequately provided information detailing substantive possibilities of "serious, chronic and lifestyle altering nature of the complications associated with its products." (Ex. G, Expert Report of Jerry G. Blavais, M.D. at 4-6, 13-14). Particularly, Defendants did not warn doctors of the chronic and debilitating pain and chronic dyspareunia as experienced by Plaintiff. *Id*; Ex. H, Deposition of Cynthia Coffey 45:13-24).

As per Dr. Blavais, Defendants also failed to inform doctors that it did not adequately study the safety and efficacy of its insertion technique it developed, which is complicated by the

fact that the product itself is difficult to "tension" in its "tension-free" insertion as it shrinks in the female patient's body over time, instead relying on the general information and experiences from the TVT product. (Ex. G at 4, 10, 14-15).

Dr. Park's conversation with Mrs. Coffey regarding possible TVT-Exact complications included that an unusual side effect of chronic pain or sexual dysfunction could occur. (Ex. C, Dep. Dr. Park at 43:22-25-44:1-5). These rates of complications were not adequately represented by the Defendants and therefore could not have been adequately presented by Dr. Park to Mrs. Coffey, with the potential complication rate of vaginal pain and dyspareunia at 7.9%. (Ex. G, Dr. Blavais Expert Report at 6). Dr. Park indicated that if the Defendants had information regarding adverse events, side effects, or safety, she would want to know that information, would expect the Defendants to provide it to her, and would have conveyed it to her patients. (Ex. C, Dep. Dr. Park 78:4-25-79:2).

Both Dr. Griffis and Dr. Park indicated that there are equally efficient and safe alternatives to the mesh procedures in the form of the Burch procedure. (Ex. B, Dep. Dr. Griffis 38:4-25-39:1-9, 116:9-20; Ex. C, Dep. Dr. Park 26:4-19). Mrs. Coffey indicated that had she known of the extent and severity of her pelvic pain issues and discomfort she has experienced due to the mesh, or how severely it would affect her relationship with her husband, she would not have gone through with the procedures. (Ex. H, Dep. Coffey 89:12-25-90:1-6).

Because Defendants failed to provide adequate information about the effects of the materials, the additional adverse events, and the frequency and severity of the adverse events, thereby insufficiently warning of the possibility of the device's dangers, the adequacy of the warnings is a question of fact, and the court should deny Defendants' motion for summary judgement.

## II. FRAUD CLAIMS

Contrary to Defendants' assertions, Plaintiffs' negligence-based claims cannot be dismissed based on the court's disposition of Plaintiff's failure to warn claims. (Def. Mt. at 8-11). Defendants attempt to assert the same arguments this Court has already disposed of in *Sanchez v. Boston Scientific, Corp.* As this Court has previously ruled, "medical device manufacturers may be liable for design defects under the ordinary principles of negligence" in California. 2014 U.S. Dist. LEXIS, at *17. Thus, the Court can swiftly reject Defendants' argument on this point. In California, negligence theories survive summary judgment even when courts dismiss failure to warn claims for lacking causation under the learned intermediary doctrine. *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086, 2013 WL 1149717, at *10, 16 (N.D. Cal. March 19, 2013) (granting defendants' motion for summary judgment on plaintiff's strict liability and negligent failure to warn claim, but denying defendant's motion for summary judgment on plaintiff's negligence claim under California law); *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1487 n. 15, 81 Cal. Reptr. 2d 252 (Cal. Ct. App. 1999) (explaining that a negligent design claim can stand alone without failure to warn claim in California because the two causes of action involve separate rights and duties). *Tucker* illustrations that California's learned intermediary doctrine does not bar every cause of action against a manufacturer or medical devices. 2013 WL 1149717. Applying *Motus I* and *Motus II*, that court granted summary judgment on the plaintiff's strict liability and negligent failure to warn claims because there was no evidence the defective warnings caused the plaintiff's injuries. *Id.* at 16. However, the learned intermediary doctrine did not bar the plaintiff's negligent design claim and that court denied summary judgment on that claim. *Id.* at *10. *Tucker* teaches that a plaintiff's negligence-based

claims survive summary judgment even when the learned intermediary doctrine bars his or her strict liability or negligent failure to warn claims.

Under *Tucker* and *Valentine*, the following negligence-based claims survive summary judgment:

1. **Negligence**: *Friedman v. Merck & Co.*, 107 Cal. App. 4th, 454, 463, 131 Cal. Rptr. 2d 885, 890 (2003);

2. **Negligent Design**: *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305, 144 Cal. Rptr.3d 326 (Cal. Ct. App. 2012);

3. **Negligent Misrepresentation**: *Apollo Capital Fund, LLC v. Roth Capital Partners, LLC*, 158 Cal. App. 4th 226, 70 Cal. Rptr. 3d 199 (Cal. Ct. App. 2007).

Summary judgment would therefore be inappropriate on Plaintiff's negligence-based claims because California's learned intermediary does not bar those claims.

Plaintiff has also offered evidence that Defendants breached their duty and did not act as a reasonable medical device manufacturer, including failing to warn physicians and patients of known risks. Plaintiff also offered evidence that Defendants engaged in extreme and outrageous conduct including but not limited to failing to inform physicians and patients of risks and complications that Ethicon knew to be associated with the Prolene Soft and TVT-Exact mesh devices. For all of these reasons, Defendants' motion for summary judgment on these claims should be denied.

## III. DESIGN DEFECT

Defendant is correct that California has eliminated strict liability for design defect claims in medical devices. *Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 183-85 (Cal. App. 2013). However, in so doing, courts have made it clear that design defect claims continue

to survive for failure to warn even in strict liability. *See Garrett*, 214 Cal. App. 4th at 183 ("Drug…manufacturers [and device makers], however, are not exempt from liability for manufacturing defects, failure to warn, and negligence."); *see also Carlin v. Superior Court*, 13 Cal. 4th 1104, 1117 (1996). The required warning must be sufficient to provide notice of any defect that a manufacturer knew or should have known existed. *See Garrett*, 214 Cal. App. 4th at 182 ("Under the negligence standard as reflected in comment k to section 402A of the Restatement Second of Torts… a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed.").

As previously described above regarding the failure to provide adequate warnings as to the Prolene Soft and TVT-Exact mesh, Defendants knew or should have known about the defects. Thus, Plaintiff raises question of fact regarding the design defects of the Prolene Soft and TVT-Exact. Their design defect claims based on Defendants' failure to provide adequate warnings are not precluded under California law, and Defendants' motion for summary judgment should be denied on this ground.

## IV. MANUFACTURING DEFECT

In light of the Court's consistent rulings across these pelvic mesh MDLs as to manufacturing defect, Plaintiff does not intend to pursue a separate claim for "manufacturing defect," as such claim has been construed by the Court (not manufactured in accordance with design, or departure from manufacturer's design specifications). *See e.g. Tyree v. Boston Scientific Corp.*, Case 2:12-cv-08633, Dkt. No. 446, pp.5-6 ("The plaintiff points to no evidence that the Obtryx sling departed from its intended design at the time it left BSC's control. Accordingly, BSC's Motion for Summary Judgment on the plaintiff's strict liability for manufacturing defect claim is GRANTED, and this claim is DISMISSED."). However, Plaintiff

does intend to present evidence that Ethicon's manufacturing process and the raw materials used in the manufacture of its Prolene Soft and TVT products resulted in defects in the product, and in support of Plaintiff's negligence, design defect, and failure to warn claims, which is consistent with the Court's prior rulings. By not contesting Ethicon's motion as to "manufacture defect," Plaintiff does not forego, waive or in any way agree that evidence relating to Ethicon's manufacturing process and raw materials are restricted in any way.

## V. NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS AND GROSS NEGLIGENCE

Defendants' motion simply recites what they claim to be the applicable burden of proof and then state that Negligent Infliction of Emotional Distress and Gross Negligence should be dismissed for lack of evidence of "extreme and outrageous conduct." (Def. Mt. at 12). Defendants attempt to purport a heightened burden of proof for these two standards that do not exist.

In *Muse v. Brands, LLC v. Gentil*, 2015 WL 4572975, at *12, the intentional infliction of emotional distress cause of action was dismissed because the court could not plausibly infer that the defendant owed plaintiffs an independent tort duty. *Muse Brands, LLC v. Gentil*, No. 15-cv-01744-JSC, 2015 U.S. Dis. LEXIS 99143, at *32-33, 36-37 (N.D. Cal. July 28, 2015). Simply, [t]he negligent causing of emotional distress is not an independent tort but the tort of negligence. The traditional elements of duty, breach of duty, causation, and damages apply. *Marlene F. v. Affiliated Psychiatric Med. Clinic, Inc.*, 48 Cal. 3d 583, 585, 257 Cal. Rptr. 98, 98, 770 P.2d 278, 278 (1989).

In addition, even if Negligent Infliction of Emotional Distress and Gross Negligence did require extreme and outrageous conduct, Plaintiff previously demonstrated such conduct in

Defendants failure to inform physicians and patients of risks and complications that Ethicon knew to be associated with the Prolene Soft and TVT-Exactg mesh devices.

As a result, Defendants' motion for summary judgment as to these counts should be denied, as no heightened burden of proof applies.[4]

## VI. FRAUD AND FRAUDULENT CONCEALMENT

Plaintiff has demonstrated the elements of her fraud claims. Plaintiff demonstrated previously that the Defendants' warnings were inadequate. Plaintiff also demonstrated that: 1) Defendants did conceal, false represent, and did not disclose the true risks of the Prolene Soft and TVT-Exact mesh; 2) Defendants did so knowingly; 3) intended to induce reliance of patients such as Mrs. Coffey (through her physicians Dr. Griffis and Dr. Park); 4) Mrs. Coffey relied on these representations (made to her physician) in obtaining adequate and accurate informed consent related to the Prolene Soft and TVT mesh; and 5) that Mrs. Coffey suffered injuries as a result.[5] Defendants motion for summary judgment on this claim should be denied.

## VII. CONSUMER PROTECTION LAW CLAIMS

Plaintiff does not intend to pursue a claim for consumer protection laws in this case, so this argument is moot.

## VIII. CONSTRUCTIVE FRAUD

Plaintiff does not intend to pursue a claim for constructive fraud in this case, so this argument is moot.

## IX. UNJUST ENRICHMENT

[4] Defendants based their arguments solely on the purported need to meet a higher standard and not an absence of evidence to support the cause of action generally, Plaintiff therefore did not further detail that supporting evidence.
[5] *City of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 345 (2006).

Plaintiff does not intend to pursue claims for unjust enrichment in this case, so this argument is moot.

## X. BREACH OF WARRANTY

Plaintiff does not intend to pursue claims for breach of warranty in this case, so this argument is moot.

## XI. LOSS OF CONSORTIUM

Mr. Coffey's claim for loss of consortium does not fail as a matter of law because it is a derivative of Mrs. Coffey's claims. (Def. Mt. at 26). Because fact issues exist on Plaintiffs' failure to warn claims addressed above, and because Plaintiffs' negligence claims survive irrespective of their failure to warn claims, Mr. Coffey's loss of consortium claims should continue. *See Vanhooser v. Superior Court*, 142 Cal. Rptr. 3d 230, 233-34 (Cal. Ct. App. 2012)

## CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court enter an Order denying Defendants' Motion for Summary Judgment.

Date: June 17, 2019

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on this date I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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